UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, and THE CITY OF NEW YORK *ex rel.* OMNI HEALTHCARE INC.,

Plaintiffs,

v.

MCKESSON CORPORATION, MCKESSON SPECIALTY CARE DISTRIBUTION CORPORATION, MCKESSON SPECIALTY DISTRIBUTION LLC, MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, L.P., ONCOLOGY THERAPEUTICS NETWORK CORPORATION, ONCOLOGY THERAPEUTICS NETWORK JOINT VENTURE, L.P., US ONCOLOGY, INC., and US ONCOLOGY SPECIALTY, L.P.,

Defendants.

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OPINION & ORDER

12-CV-6440 (NG) (LB)

GERSHON, United States District Judge:

Relator Omni Healthcare Inc. ("Omni") brings this *qui tam* action on behalf of the United States, 30 states, the District of Columbia, and the cities of New York and Chicago against McKesson Corporation ("McKesson") and 7 of McKesson's corporate subsidiaries (collectively "defendants") alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, analogous state statues, and the common law. Defendants move to dismiss the Second Amended

Complaint ("SAC") in its entirety under Federal Rule of Civil Procedure 12(b)(6), principally arguing that the FCA's "first-to-file" provision bars the action. Secondarily, defendants argue that any claims involving submissions of false claims by an entity another than Omni should be dismissed as not plead with sufficient particularity, as required under Rule 9(b). Finally, defendants argue that certain claims should be dismissed because they fail to state a claim for relief, and/or are time barred, and/or Omni lacks standing to assert them. For the following reasons, defendants' motion is granted in part and denied in part.

I. Factual Allegations

The following facts are drawn from the SAC and are assumed to be true for the purposes of this motion.

1. General Nature of the Action

Relator Omni alleges that the defendants have engaged in misconduct in the use of "overfill" in vials of injectable drugs intended for the treatment of cancer patients. "Overfill" is the amount of a drug in excess of the amount indicated on the label. Manufacturers of injectable drugs must include some amount of overfill to ensure that the medical provider administering the drug is able to withdraw a full dose from the vial. The central allegation in this action is that defendants intentionally broke into vials of injectable drugs, harvested the dosage and overfill, and then sold syringes, including the overfill, to non-defendant medical providers who wrongfully billed government programs for the overfill. As detailed below, relator Omni alleges that the defendants' conduct not only caused the submission of fraudulent claims, including by Omni itself, but also had negative consequences for patient safety, resulted in the distribution of adulterated and misbranded drugs, and provided an unlawful kickback to medical providers who purchased prefilled syringes. The drugs at issue in this case include Aloxi, Procrit, Aranesp, Neupogen, Taxotere, and Kytril in

both the brand and generic forms (the "Oncology Drugs"). Defendants engaged in this conduct from 2001 through at least 2010.

2. Parties

Relator Omni is a professional medical company based in Florida. Through its principals, who are physicians, Omni practices internal medicine with subspecialties in hematology and oncology and regularly treats cancer patients. In connection with its treatment of cancer patients, Omni purchases injectable drugs from pharmaceutical distributors and wholesalers.

Defendant McKesson is a Delaware corporation headquartered in California. McKesson is one of the largest pharmaceutical distributors in North America.

Defendant US Oncology, Inc. is a Delaware corporation headquartered in Texas that provides drug distribution and specialty pharmacy services. McKesson purchased US Oncology, Inc. and its subsidiary, US Oncology Specialty, L.P. in December 2010. US Oncology Specialty, L.P., is a pharmaceutical distributor specializing in oncology drugs.

The remaining defendants are other subsidiaries of McKesson. McKesson Specialty Care Distribution Corporation ("McKesson Specialty") is a health care services company that distributes medical supplies and pharmaceutical products to the health care industry, including to specialty medical providers such as oncologists. McKesson Specialty is the successor to defendant McKesson Specialty Care Distribution Joint Venture, L.P., which is itself the successor-in-interest to defendant Oncology Therapeutics Network Joint Venture, L.P. Defendant Oncology Therapeutics Network Corporation ("OTN") was a specialty pharmaceutical distribution corporation that acted as a general partner of Oncology Therapeutics Network Joint Venture, L.P. In October 2007, McKesson acquired all outstanding shares of OTN and integrated OTN with its existing businesses.

3. Pharmaceutical Distribution, Regulation, and Reimbursement

Each of the Oncology Drugs was manufactured by an original manufacturer, whose conduct in producing, handling, packaging, and labeling its drug products was subject to a comprehensive regime of regulation. The following companies manufactured the drugs at issue in this case: Aloxi was manufactured by Eisai, Inc.; Aranesp and Neupogen were manufactured by Amgen, Inc.; Procrit was manufactured by Ortho Biotech, Inc.; Kytril was manufactured by Roche Pharmaceuticals; and Taxotere was manufactured by Sanofi Aventis.

In general, the original manufacturers sold the Oncology Drugs they produced to wholesale distributors who provided the operational infrastructure—such as warehouse facilities, distribution vehicles, and inventory control systems—necessary to distribute the drugs further. The wholesale distributors sold the drugs either to pharmacies or directly to health care providers.

As wholesale distributors and specialty pharmacies in the oncology industry, defendants purchased the Oncology Drugs from the manufacturers and provided the Oncology Drugs to health care providers who administered them to patients and sought reimbursement from government programs. Defendant US Oncology, Inc. maintained affiliations with physicians and submitted its own claims for reimbursement on behalf of those physicians.

The government programs that reimbursed the claims included various federal medical assistance and health care programs and state-administered Medicaid programs. The state-administered programs were financed with a combination of federal and state funds. Although detailed in the SAC, the specifics of each program are not relevant to the resolution of the present motion. For all of the programs at issue, medical services and supplies were reimbursable only if they represented expenses actually incurred by a health care provider. Because health care

providers incurred no costs for overfill, it was not reimbursable. Additionally, only FDA-approved drugs were reimbursable. Adulterated or misbranded drugs were not reimbursable.

The Oncology Drugs were subject to regulation by the U.S. Food and Drug Administration ("FDA"), which administers the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* and promulgates regulations relating to the approval, manufacture, labeling, and distribution of drugs. Before a new drug may be marketed in the United States, the FDA must approve the drug as safe and effective for its intended use. The sponsor of a new drug makes a formal application to the FDA to approve the new drug for use in the United States by submitting, in the case of conventional drugs, a New Drug Application ("NDA"), under 21 U.S.C. § 355(b)(1), or, in the case of biologic drugs, a Biologics License Application ("BLA"), under 42 U.S.C. § 262(a). An NDA must include a description of the methods used in, and the facilities and controls used for, the drug's manufacture, processing, and packaging. The FDA also reviews a new drug's labeling information and container closure system as part of an NDA. Similarly, a BLA must include information concerning manufacturing methods and a sample of the product's label, container, and closure. 21 C.F.R. § 601.2(a). Once it approves a product for marketing, the FDA requires that manufacturers notify it of changes in the conditions established in the NDA or BLA.

The FDA publishes Current Good Manufacturing Practices ("CGMPs") which set forth minimum requirements for processing, packing, and holding drugs. The CGMPs provide standards for, among other things, the personnel engaged in quality control, the maintenance of manufacturing facilities and equipment, and the testing of in-process drugs. Drug manufacturers demonstrate compliance with the CGMPs through written documentation subject to FDA review. Drugs that are not manufactured in compliance with the CGMPs are deemed to be adulterated.

The FDA also regulates repackaging of drugs. Repackaging differs from drug compounding practiced by licensed pharmacists, which is the practice of mixing a drug to create a medication tailored to an individual patient. Drug repackagers must register with the FDA and repackaged drugs are generally subject to the regulations described above, including the CGMPs. When repackagers manipulate drugs beyond the approved intended uses, it results in new products whose safety and effectiveness have not been established, and thus the new drug lacks whatever approval the original drug may have had.

The United States Pharmacopeial Convention is a scientific non-profit organization that publishes the United States Pharmacopeia ("USP"). The USP establishes professional standards for the identity, strength, quality, and purity of drugs, as well as professional standards for compounding drugs identified as sterile. The USP requires that vials of injectable drugs contain overfill in slight excess of the labeled volume to permit withdrawal and administration of the label amount. The USP recommends that vials of the Oncology Drugs contain up to an additional .1 milliliter, or 10% overfill. Many manufacturers, however, include additional overfill to ensure that patients receive the proper amount from the vial.

Drugs are identified and reported using a National Drug Code ("NDC"), a unique, ten-digit, three-segment number that identifies a drug's labeler, product, and trade package size. The FDA publishes NDC numbers and the corresponding information in a national directory. A drug is considered misbranded if its labeling is false or misleading in any way or if use in accordance with the labeling would be dangerous to a patient's health. Additionally, the USP requires that sterile drugs bear an expiration date derived from tests conducted on samples stored in the immediate container closure system in which the drug is marketed.

Federal regulations set minimum requirements for drug storage, handling, and associated recordkeeping. Facilities used for drug storage must meet certain structural requirements, be maintained appropriately, and be secure. When required by a drug's labeling or the USP, the regulations also require that the drug be stored at the proper temperature. When not otherwise indicated, a drug may be held at controlled room temperature.

4. Allegations of Defendants' Wrongdoing

a. Manufacturing, Repackaging, and Distribution of Injectable Oncology Drugs

Defendants developed an intentional scheme (the "Prefilled Syringe Program") under which FDA requirements, as well as the CGMPs and USP guidelines, for manufacturing, processing, labeling, packing, and holding drugs were intentionally disregarded. Defendants acquired the Oncology Drugs in FDA-approved packaging from the original manufacturers. In at least two facilities, in Frisco, Texas and Memphis, Tennessee, defendants removed the Oncology Drugs from the sterile, preservative-free glass vials, pooled the drugs and their overfill, and transferred the drugs into plastic syringes. Defendants then relabeled the now-prefilled plastic syringes with altered NDC numbers, and then packaged and shipped the syringes. One of Omni's principals witnessed defendants engaging in this conduct at the Frisco, Texas facility during a meeting with several OTN executives on or about August 28, 2007. Additionally, the staff of physicians affiliated with defendant US Oncology, Inc., engaged in similar pooling and transferring of the Oncology Drugs and their overfill at the offices of those physicians.

Defendants' "repackaging" facilities and personnel, whether licensed or not, did not comply with the relevant CGMPs for: personnel engaged in quality control; the construction, cleaning, and maintenance of equipment; the storage, inspection, and testing of drug components and containers; the control of production and process, including in-process product testing; control

of packaging, labeling, storage, and distribution; laboratory controls; recordkeeping; and procedures for handling of returned and salvaged product. Similarly, defendants' facilities and personnel did not comply with USP standards for: cleaning and disinfecting areas; clean room surfaces and air filtration; action levels for microbial contamination; training of personnel; and gloved fingertip sampling. Defendants' facilities concealed issues that would have led the government to deny or withdraw registration.

On information and belief, defendants did not store the Oncology Drugs at appropriate temperatures or under appropriate conditions as specified on the labeling of the drugs, or in the then-current editions of the USP. Additionally, on information and belief, defendants did not use appropriate equipment, maintain records, or perform testing to ensure the safety, identity, strength, quality, or purity of the Oncology Drugs repackaged into prefilled syringes.

In many cases, the Oncology Drugs were originally packaged without preservatives in sterile, single-use vials. The single-use vials were designed to be punctured once and the drug dose extracted and administered in a single injection. Puncturing a vial more than once exposed the drug to a risk of contamination. The package insert for Procrit, as an example, stated: "Use only one dose per vial; do not re-enter the vial. Discard unused portions. Contains no Preservatives." (SAC ¶ 157). Relatedly, in 2001, the Centers for Disease Control and Prevention issued recommendations warning: "Intravenous medication vials labeled for single use . . . should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial." (SAC ¶ 164).

Defendants' practice of de-capping the vials in a non-aseptic environment, entering a single-use vial multiple times, and pooling the Oncology Drugs into larger syringes exposed the

drugs to potential contamination and destroyed the documented sterility of the original vials. Additionally, by pooling drugs from myriad vials to make a series of prefilled syringes, defendants destroyed the pedigree of the drugs. As a result, the source of an infection from a prefilled syringe could not be traced. Defendants concealed the nature of the drugs from providers on both the invoice and the pedigree. The invoice for a single-dose vial and a prefilled syringe each stated that the specific unit was obtained directly from the manufacturer.

Defendants' practices also compromised the Oncology Drugs' expiration date information. Defendants distributed the prefilled syringes either without expiration dates or with fabricated expiration dates that did not correspond with the expiration dates on the original vials. Further, because defendants distributed the Oncology Drugs in plastic syringes not designed for storage, the conditions relevant to a drug's expiration date were altered. For example, Aloxi when drawn into a syringe is safe and effective for only forty-eight hours at room temperature.

Health care providers ordered prefilled syringes from defendants by emailing or faxing a specific order form. The order form did not allow health care providers to include patient-specific information when ordering prefilled syringes. Relator Omni placed orders for prefilled syringes up until 6:00 pm on a given day and received the syringes the following day. Omni infers that this quick turnaround time reflected defendants' practice of mass producing prefilled syringes in advance of orders and without a valid prescription for a specific patient.

Defendants' Prefilled Syringe Program resulted in "major changes" to the repackaged Oncology Drugs such that FDA approval would have been required to distribute the drugs. As no such approval was obtained, defendants' distribution of the prefilled syringes was unapproved. Further, as defendants represented the prefilled syringes to be the same as the drug in the original vial, the drugs were misbranded.

b. Payment of Kickbacks and Manipulation of the Average Sales Price

Defendants sold prefilled syringes to health care providers through contractual agreements that provided discounts to the providers in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a–7b(b). For example, in or around September 2007, defendants charged $327.42 for a prefilled syringe of Procrit, whereas a vial of Procrit cost $346.99. This discount was made possible through the "free" overfill, for which defendants had not paid the original manufacturers. The discount amounted to a kickback to the health care providers; however, defendants advised health care providers that this practice was legal.

Defendants' conduct also had the effect of artificially inflating the Average Sales Price ("ASP") of the Oncology Drugs. The Centers for Medicare and Medicaid, an agency of the U.S. Department of Health and Human Services, bases its reimbursement rates for injectable drugs on the ASP. The ASP represents the drug manufacturer's total sales divided by the total number of units sold during a particular quarter. The total sales figure is adjusted to account for any price concessions, discounts, or rebates. The total units figure is calculated based on the amount of product as reflected on a product's FDA-approved label; thus overfill is not included in the ASP calculation.

Defendants skewed the ASP "by introducing into commerce drug product specifically excluded from the calculation of the ASP, namely, overfill, and failing to report the lower prices that defendants charged for drug product in pre-filled syringes." (SAC ¶ 23). The SAC provides a hypothetical example demonstrating how the sale of overfill would skew the ASP but does not provide any specific figures regarding the ASPs for any of the Oncology Drugs during the period of time defendants operated the Prefilled Syringe Program.

5. Exhibits

Omni attached the following exhibits to the SAC: 1) an undated letter from Amgen, Inc. to health care providers describing an outbreak of bacteremia among patients receiving Epogen; 2) invoices from December 2007 to March 2010 showing Omni's purchase of Oncology Drugs from OTN; 3) McKesson "Prefilled Syringe Order Forms" showing orders by Omni of Procrit and Aloxi between September 2009 and March 2010; 4) an email dated September 4, 2009 from a "McKesson Specialty Care Solutions" representative to an Omni principal explaining how to order prefilled syringes; 5) an email dated November 5, 2007 from an OTN employee stating that manufacturer contract prices for Procrit and Aloxi had changed; 6) Eisai's product price list, effective July 20, 2012; 7) twenty-four Medicare claims submitted by Omni between January 2007 and December 2010.

6. The Federal Claims

Omni bring four federal claims under the FCA. First, Omni alleges that defendants, for the purpose of defrauding the government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicare, Medicaid, and other government health programs in violation of 31 U.S.C. § 3729(a)(1) (1994).[1] Second, Omni alleges that defendants knowingly made, used or caused to be made or used, false records or statements to get a false claim paid in violation of 31 U.S.C. § 3729(a)(2). Third, Omni alleges that defendants knowingly made, used, or caused to be made or used false records or false statements to conceal

[1] Citations in the SAC refer to the version of 31 U.S.C. § 3729 in effect until amended on May 20, 2009 by the Fraud Enforcement and Recovery Act of 2009. Although some of the conduct described in the SAC occurred after the amendment, the parties have cited only to the earlier version of the statute in their papers. As the amendment does not appear to affect the issues discussed in this opinion—and the parties do not argue otherwise—I also cite to the pre-2009 statute.

an obligation to refund the government in violation of 31 U.S.C. § 3729(a)(7); a claim of this nature is often called a "reverse false claim." Fourth, Omni alleges that defendants conspired to violate the FCA, including by jointly marketing prefilled syringes, in violation of 31 U.S.C. § 3729(a)(3).

7. The State Law Claims

Omni brings 35 state law claims concerning 30 states, 2 cities, and the District of Columbia alleging violation of various FCA analogs. Omni brings one claim under the law of each jurisdiction, except for New Mexico and Tennessee, for which Omni brings two under each state's law. Each of the state law claims contains a similar allegation, namely, that defendants knowingly presented and/or caused to be presented false claims for payment under the applicable state-funded program and that defendants knowingly made and/or caused to be made false records or statements in connection with the false claims.

8. The State Common Law Claims

Omni brings two claims under the common law of unidentified states for payment under mistake of fact and unjust enrichment. The mistake of fact claim alleges that the governments (federal, state, and local) made payments for prefilled syringes under a mistake of fact, caused by defendants, that the claims were for the FDA-approved drugs contained in vials. The unjust enrichment claim alleges that defendants unjustly enriched themselves at the expense of the governments "under circumstances where it would be inequitable . . . to retain the benefits conveyed." (SAC ¶ 259).

II. Procedural History

On March 9, 2012, Omni filed a *qui tam* Complaint under seal alleging FCA violations by AmerisourceBergen Corporation ("ABC") and three affiliated companies (collectively "ABC

defendants"). On October 9, 2012, Omni filed, also under seal, its First Amended Complaint ("FAC") making the same substantive allegations as the Complaint and adding as defendants McKesson, OTN, and US Oncology, Inc. The United States later intervened with respect to certain claims against the ABC defendants. Upon relator's motion, this action was severed from the ABC action on March 28, 2018. On April 3, 2018, Omni publicly filed the SAC adding two new federal claims, two new state statutory claims (under Vermont and Washington law), and five additional McKesson subsidiaries as defendants: McKesson Specialty, McKesson Specialty Care Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P.[2]

III. Discussion

1. FCA Framework

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval" or any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(1)–(2). "Rather than rely solely on federal enforcement of these provisions, Congress decided to deputize private individuals, encouraging them to come forward with claims on behalf of the Government in the form of *qui tam* suits." *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 166 (2d Cir. 2018). The FCA's *qui tam* provisions allow a private party, called the relator, to challenge "fraudulent claims against the Government on the

[2] On June 20, 2018, I issued a limited unsealing order allowing defendants to review the Complaint and the FAC. On December 7, 2018, I granted Omni's unopposed motion to unseal all entries on this case's docket filed after April 3, 2018. Because the parties had filed copies of the Complaint and the FAC as sealed exhibits to their memoranda of law concerning this motion, my order operated to unseal those documents.

Government's behalf, ultimately sharing in any recovery." *Id.* (internal citations and alterations omitted). The government may intervene in any *qui tam* action, "in which case the action shall be conducted by the Government," and the relator's recovery thereby reduced, or it may decline to take over the action, in which case the relator "shall have the right to conduct the action." 31 U.S.C. § 3730(b)(4)(A), (d)(1), (b)(4)(B).

The FCA includes several limiting provisions. Relevant to this motion is the provision known as the "first-to-file bar," which provides that "[w]hen a person brings an action under [the FCA], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." *Id.* § 3730(b)(5). "The command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." *Wood*, 899 F.3d at 167 (quoting *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011)). The rule "ensures that only one relator shares in the Government's recovery and encourages potential relators to file their claims promptly." *Id.* (citing *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)).

2. First-to-File Bar

Defendants argue that this entire action should be dismissed under the first-to-file bar because Omni's allegations are "indistinguishable" from an earlier filed *qui tam* action, *United States ex rel. Underwood v. Amgen, Inc.*, 10-cv-2441 (SLT) (SMG). Omni agrees that *Underwood* was pending when this action was filed but argues that the first-to-file bar is inapplicable because *Underwood* alleged a different fraudulent scheme and thus is not related to this action.

In the recent case *United States ex rel. Wood v. Allergan, Inc.*, the Court of Appeals for the Second Circuit discussed the standard for evaluating whether actions are related for purposes of the first-to-file bar:

> A second action is "related," within the meaning of Section 3730(b)(5), if the claims incorporate the same material elements of fraud as the earlier action, even if the allegations incorporate additional or somewhat different facts or information. In other words, to be related, the cases must rely on the same essential facts. If the first-filed complaint ensures that the Government would be equipped to investigate the fraud alleged in the later-filed complaint, then the two cases are related within the meaning of Section 3730(b)(5).

Wood, 899 F.3d at 169 (internal quotation marks, alterations, and citations omitted).

The first-to-file bar "bears on the merits of whether a plaintiff has stated a claim" and thus must be analyzed under Federal Rule of Civil Procedure 12(b)(6). *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 85 (2d Cir. 2017). Under this rule, the court must accept as true all well-pleaded factual allegations and must draw all inferences in plaintiff's favor. *Swiatkowski v. Citibank*, 446 Fed. Appx. 360, 360–61 (2d Cir. 2011). To survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Facial plausibility exists when a plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint and documents attached to the complaint as exhibits. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002).

Keeping in mind the Second Circuit's direction that an action is related if it "incorporate[s] the same material elements of fraud as the earlier action," I review the *Underwood* complaint. *Wood*, 899 F.3d at 169. That complaint, filed under seal on May 28, 2010 in this district, brought FCA and analogous state laws claims against 50 defendants, including the drug manufacturer

Amgen, Inc., 12 other drug manufacturers, 23 drug repackagers, and 14 health care providers.[3] The only *Underwood* defendant who is also a defendant in this action is US Oncology, Inc. The allegations in *Underwood* were based on the observation of the relator in that action during his employment with one of the defendant drug manufacturers between 1986 and 2005. The complaint summarized its allegations as follows:

> Although expansive in scope, the fraudulent scheme is straightforward. With the knowledge and participation of Defendant Health Care Providers and Manufacturers, Defendant Repackagers unlawfully manipulated the licensed biologic drugs by repeatedly entering single-use and multi-use vials, extracting and/or pooling the overfill, and repackaging the product into smaller doses that are re-labeled and placed in interstate commerce for delivery to health care providers. (*Underwood* Compl. ¶ 7).
>
> Defendant Manufacturers have participated in the scheme. Driven by competition and the desire to increase market share, Defendant Manufacturers routinely fill containers of licensed biologic product . . . in amounts greater than the FDA labeling quantities or the dose to be administered to a patient. . . . Defendant Manufacturers illegally market the overfill to health care providers as an excess, free biologic product that had been recaptured, repackaged, administered to patients, and billed to the Federal Payer Programs. With the assistance of Defendant Repackagers or through in-house pharmacies, *providers pool the overfill amount from one or more doses to create additional doses, as well as divide and re-manufacture the single-use vials to create smaller doses that are administered to patients. Id.* ¶ 8–9 (emphasis added).
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> Defendant Health Care Providers were encouraged to and in fact did seek reimbursement from the Federal Payer Programs for the repackaged drugs. In so doing, *providers have billed the Federal Payer Programs for the repackaged product by, for example, purchasing one single-use dose, but billing for more than one dose by illegally repackaging the finished product.* The conduct results in illegal kickbacks and price concessions concealed from federal and state governments. *Id.* ¶ 10 (emphasis added).

Because US Oncology, Inc. is categorized in *Underwood* as a health care provider defendant, all of the allegations against that group of defendants are applicable to it, including, that it "unlawfully remanufacture[s] the drugs in-house . . ., administer[s] them to patients, and bill[s]

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[3] On April 29, 2016, the United States declined to intervene in *Underwood*. The case was unsealed on May 11, 2016 and voluntarily dismissed without prejudice on September 7, 2016.

them to the Federal Payer Programs." (*Id.* ¶ 159(D)). Additionally, the *Underwood* complaint specifically alleged that "US Oncology knowingly purchases repackaged biologic drugs for administration to patients and/or manipulates and repackages licensed finished biologic drugs internally in violation of the FDCA and [Public Health Services] Act." (*Id.* ¶ 76).

Defendants here argue that this case must be dismissed in its entirety because *Underwood*'s allegations "were more than sufficient to enable the Government to investigate *any entity* that created, distributed, or used pre-filled syringes of injectable drugs." (Defs.' Mem. at 3 (emphasis added)). Although counsel for defendants moderated this position under questioning at oral argument, it is important to reject this overbroad argument, which potentially immunizes unrelated defendants from *qui tam* liability. Instead, I must compare the specific allegations in this case to the *Underwood* complaint, and having done so, I conclude that the allegations are related only as to defendant US Oncology, Inc.

The FAC, like the complaint in *Underwood*, alleges that US Oncology, Inc. engaged in specific fraudulent conduct concerning overfill of injectable cancer drugs.[4] Both describe how US Oncology, Inc. harvested overfill from sterile vials and repackaged the overfill in prefilled syringes in violation of the CGMPs and USP standards.[5] The two cases allege that this conduct occurred

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[4] In assessing relatedness, I compare *Underwood* to the FAC because that is the earliest filed complaint in this action bringing claims against any of the present defendants. *See United States ex rel. Hanks v. Amgen, Inc.*, 336 F. Supp. 3d 90, 116 (E.D.N.Y. 2018) (citing *Wood*, 899 F.3d at 172). Although at oral argument both parties agreed that the FAC is the operative complaint for the issue of relatedness, the parties' papers took different positions. Defendants assumed, without analysis, that I should compare the SAC. Omni argued in a footnote to its memorandum of law that I should use the original Complaint, which did not name any of the present defendants, yet discussed the SAC in its above-the-line argument.

[5] Although I base my decision as to relatedness on the FAC, I note that the SAC reinforces the conclusion that this action and *Underwood* describe the same conduct by US Oncology, Inc. The SAC adds that US Oncology, Inc. administered prefilled syringes containing overfill to patients and itself filed false claims. (SAC ¶ 146). These same allegations appear in *Underwood*. (*Underwood* Compl. ¶ 159(D)).

during overlapping periods of time and with respect to overlapping groups of drugs.[6] However, there need not be perfect identify between every factual element of related frauds. *See, e.g.*, *U.S. ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Baxter Healthcare Corp.*, 772 F.3d 932, 940 (1st Cir. 2014) (additional drugs); *U.S. ex rel. Chovanec v. Apria Healthcare Grp. Inc.*, 606 F.3d 361, 365 (7th Cir. 2010) (differing time periods). All that is required is that the cases "rely on the same essential facts." *Wood*, 899 F.3d at 169. I conclude that, because *Underwood* disclosed that defendant US Oncology, Inc. engaged in the same fraudulent conduct, with respect to injectable oncology drugs, during an overlapping time period, Omni's claims against US Oncology, Inc. are related to *Underwood*, and consequently barred by it.[7]

Although I conclude that the claims against US Oncology, Inc. are related to *Underwood*, I reach the opposite conclusion with respect to the claims against the other defendants. *Underwood* did not name any of those defendants or provide any facts that might associate them with the conduct described. The identity of the defendant is a crucial fact bearing on whether two fraud claims are related. *In re Nat. Gas Royalties Qui Tam Litig. (CO2 Appeals)*, 566 F.3d 956, 962 (10th Cir. 2009). Consequently, the first-to-file bar would not reach a subsequent *qui tam* action otherwise alleging the same material elements of fraud, but alleging those elements concerning different defendants. *See id.* ("Two complaints can allege the very same scheme to defraud the very

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[6] Three of the six Oncology Drugs in this action were expressly identified in *Underwood*, which in total identified twenty-one biologic drugs.

[7] I note that the FAC might allow for a reading that would distinguish some of its claims against US Oncology, Inc. from those in *Underwood*. That reading is that the claims against US Oncology, Inc. only begin in December 2010 when it was acquired by McKesson. In that case, the FAC would cover a different set of facts from *Underwood*, namely, US Oncology, Inc's participation, in concert with McKesson and other affiliates, in an intra-McKesson fraud concerning overfill. *See U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 219 (D.C. Cir. 2003). However, on oral argument, Omni expressly disclaimed this reading of the FAC and made clear that it was suing US Oncology, Inc. for conduct that occurred before it was acquired by McKesson. (Tr. 32:10–34:6, Jan 10, 2019).

same victim, but they are not the same claim unless they share common defendants.). Omni asserts, and defendants have not refuted, that there is indeed no authority that holds that a *qui tam* complaint alleging a particular fraudulent scheme bars all other cases in which other unrelated defendants commit an entirely independent fraud involving the same elements.

Defendants argue, however, that McKesson's 2010 acquisition of US Oncology, Inc. associates McKesson with US Oncology, Inc. such that *Underwood* implicated McKesson. But the factual and procedural timeline contradicts that conclusion. *Underwood* concerned conduct that its relator observed between 1986 and 2005. McKesson purchased US Oncology, Inc. years later in December 2010, months after the complaint in *Underwood* was filed. While the government may well have continued its investigation of US Oncology, Inc. past the period ending in 2005, it is not reasonable to conclude that *Underwood*'s allegations against US Oncology, Inc. "ensure[d] that the Government 'would be equipped to investigate'" a separate fraud by McKesson. *Wood*, 899 F.3d at 169 (quoting *United States ex rel, Health v. AT&T, Inc.*, 791 F.3d 112, 121 (D.C. Cir. 2015)).

Finally, I address defendants' argument that the recently unsealed case, *United States ex rel. Mullen v. AmerisourceBergen Corp.*, 10-cv-4856 (NG) (ST), filed in this district on October 21, 2010, supplies the missing link to associate McKesson and OTN with the conduct described in *Underwood*.[8] Defendants argue that federal authorities could have read *Mullen* and *Underwood* together to conclude that McKesson and its subsidiaries were engaged in the fraud described in this action—and thus the government was "equipped to investigate" McKesson. *Mullen* alleged FCA violations against ABC, a drug wholesaler that is a McKesson competitor. None of the

[8] Although defendants first raised *Mullen* in their reply, I do not fault them for doing so as the complaint in that case was under seal at the time they filled their moving memorandum of law. I allowed Omni to file a surreply on the issue.

defendants in this action was a defendant in *Mullen*, nor were they identified as unnamed co-conspirators. Yet, defendants argue that *Mullen* should have alerted the government to McKesson's alleged fraud because the corporate-parent defendant in *Mullen*, ABC, operates a similar business with a similar business structure to McKesson.

I reject defendants' argument. To be "equipped" to investigate a fraud, the government must know whom to investigate. Certainly, there are cases where unnamed parties were so closely linked to named defendants that the government had notice to investigate. *See CO2 Appeal*, 566 F.3d at 962; *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1280 n.4 (10th Cir. 2004). Here, no connection is alleged between any *Mullen* defendant and McKesson other than that they were similarly situated in terms of their business structures. The allegations against ABC thus reveal nothing related to this case. *See United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 373 (5th Cir. 2009) (rejecting the notion that within an industry "suit as to one is suit as to all"). Accordingly, I conclude that the first-to-file bar does not prevent this action from proceeding as to any defendant other than US Oncology, Inc.

3. Rule 9(b)

Defendants move to dismiss Omni's claims under § 3729(a)(1) and § 3729(a)(2) on the ground that they were not pled with the particularity required by Federal Rule of Civil Procedure 9(b). "*Qui tam* complaints filed under the FCA, because they are claims of fraud, are subject to Rule 9(b)," which requires a plaintiff to plead fraud claims with particularity. *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017). Generally, to comply with Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* (citations omitted). However, an FCA complaint "can satisfy

Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Id.* at 86. Rule 9(b) permits scienter to be averred generally, but a relator must "plead the factual basis which gives rise to a strong inference of fraudulent intent." *United States ex rel. Tessler v. City of New York*, 712 F. App'x 27, 29 (2d Cir. 2017) (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)).

To state a claim under § 3729(a)(1) a relator must show that the defendant "(1) made [or caused to be made] a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 43 (2d Cir. 2016) (quoting *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001)), *abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. — (2016). To state a claim under § 3729(a)(2) a relator must show that defendants "knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim." *United States ex rel. Piacentile v. Amgen, Inc.*, 336 F. Supp. 3d 119, 135 (E.D.N.Y. 2018) (quoting *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 335 (9th Cir. 2017)).

Defendants argue that allegations about false claims submitted by any entity other than Omni itself fail because the SAC contains no information about the content of such claims, who submitted them, and when they were submitted. However, such information is not required where, as here, the relator's allegations create a strong inference that specific false claims were submitted. *Chorches*, 865 F.3d at 82. Omni has detailed an extensive scheme whereby defendants caused health care providers to submit claims to government health programs for drugs that were not

eligible for reimbursement.[9] Omni has described how defendants marketed their fraudulent "Prefilled Syringe Program" to health care providers, identified the six drugs that were part of the scheme, and provided an approximate timeframe. The information that would permit further identification of the false claims is the identity of the healthcare providers who ordered prefilled syringes. This information is within defendants' knowledge. Thus, Omni has satisfied the particularity requirement.

It is also worth emphasizing that "[i]t is not the purpose of Rule 9(b), as applied to FCA *qui tam* actions, to render the FCA toothless as to particularly clever fraudulent schemes." *Id.* at 86. Given the structure of the fraud in this case, requiring relator to plead the content of the false claims is unnecessary.

4. Failure to State a Claim

The allegation under § 3729(a)(7) for "reverse false claims" fails, as the basis for this claim is exactly the same as the basis for the claim under § 3729(a)(1) for presentation of false claims.[10] Characterizing the receipt and retention of federal money as two different claims is "redundant—two ways of describing the same transaction." *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 339 (S.D.N.Y. 2004). Omni does not allege any conduct that would have resulted in the retention of federal money that is not the same conduct that caused the payment of false claims. Accordingly, the claim under § 3729(a)(7) is dismissed.

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[9] Contrary to defendants' assertions, Omni has pled sufficient facts, which are assumed to be true for purposes of this motion, to show that claims for prefilled syringes containing overfill would have been false and that defendants' actions could have inflated the ASP. It is not necessary that Omni plead what the ASP would have been if not for defendants' actions.

[10] "A reverse false claim is any fraudulent conduct that results in no payment to the government when a payment is obligated." *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 88 (D.D.C. 2014) (citations and internal quotations omitted).

The claim for civil conspiracy under § 3729(a)(3) is also dismissed. A parent corporation and its wholly owned subsidiaries are "legally incapable of forming a conspiracy with one another." *U.S. ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 528 (D. Md. 2006), *aff'd in part, dismissed in part*, 237 F. App'x 802 (4th Cir. 2007) (citing *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984)). On that basis, there can be no conspiracy among any of the remaining defendants after October 2007 when McKesson acquired OTN. Prior to that time, a conspiracy claim might lie if the relator had plead, as to McKesson and OTN, "an agreement to defraud the government . . . coupled with any act to get a false or fraudulent claim allowed or paid." *Taylor*, 345 F. Supp. 2d. at 331 (citations and internal quotations omitted). However, this is not alleged in the SAC. Rather, the SAC describes only that McKesson acquired OTN for the purpose of more efficiently operating the fraudulent Prefilled Syringe Program. (SAC ¶ 26). The SAC does not describe any joint conduct by McKesson and OTN prior to the acquisition that might show an implicit agreement to defraud the government. Accordingly, the claim under § 3729(a)(3) is dismissed.

5. Statute of Limitations

In general, a relator must bring an FCA *qui tam* action within six years of a violation.[11] 31 U.S.C. § 3731(b)(1). Defendants argue that the claims and defendants added in the SAC are time barred. (Defs.' Mem. at 22). Omni concedes that its SAC will be timely only if it relates back to the FAC. And, as I have already concluded that the newly asserted FCA claims, reverse false claims and conspiracy, fail under Rule 12(b)(6), I need not consider whether those claims would

[11] The FCA offers a potentially longer statute of limitations in 31 U.S.C. § 3731(b)(2). Here, neither party argues that this provision is applicable.

relate back under Rule 15(c)(1)(B). I consider only whether Omni's claims against five McKesson subsidiaries, who were first added as defendants in the SAC, relate back to the FAC. [12]

An amended complaint adding a new party must meet the following criteria under Rule 15(c)(1)(C) to relate back:

> (1) the claim must have arisen out of conduct set out in the original pleading; (2) the party to be brought in must have received such notice that it will not be prejudiced in maintaining its defense; (3) that party should have known that, but for a mistake of identity, the original action would have been brought against it; and (4) the second and third criteria are fulfilled within [90] days of the filing of the original complaint and the original complaint was filed within the limitations period.

Hogan v. Fischer, 738 F.3d 509, 517 (2d Cir. 2013) (citations and alterations omitted). The application of this rule to an FCA action presents a paradox because "[b]y design, the seal provision of § 3730(b) deprives the defendant in an FCA suit of the notice usually given by a complaint." *United States v. Baylor Univ. Med. Ctr.*, 469 F.3d 263, 270 (2d Cir. 2006). Even the defendants who were actually named in the FAC did not receive notice of it until I ordered its limited unsealing, which was after the SAC itself had been served. Thus, one might argue, the new defendants were not deprived of any notice they might have received had they been named in the FAC.

However, the statute expressly allows a timely complaint to satisfy the statute of limitations with respect to named defendants although those defendants are deprived of notice. *See* 31 U.S.C. § 3730(b)(2) ("[T]he complaint . . . shall not be served on the defendant until the court so orders."). As the court in *Hayes v. Department of Education of New York* explained, "[N]o claim actually pleaded in the Amended Complaint would be time-barred, if timely when the original sealed

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[12] Defendants raise no objection to two name changes in the caption. The FAC named "Oncology Therapeutics Network" and "U.S. Oncology." The SAC changed those names to "Oncology Therapeutics Network Corporation" and "US Oncology, Inc."

complaint was filed." 20 F. Supp. 3d 438, 445 (S.D.N.Y. 2014). There is no such provision in the statute that supports depriving a party not named in the filed complaint of notice. On the contrary, the Second Circuit stated, although in the context of amending claims under Rule 15(c)(1)(B), that the secrecy requirements of the FCA's sealing provision are incompatible with relation back because "the touchstone for relation back . . . is notice." *Baylor*, 469 F.3d at 270. Therefore, the claims asserted against McKesson Specialty Care Distribution Corporation, McKesson Specialty Care Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P. are dismissed as untimely. I note that my conclusion here is consistent with my focus, in my analysis of the first-to-file bar, on whether the earlier filed complaint identified the defendant at issue. The statute of limitations, like the first-to-file bar, encourages relators to come forward promptly with information to help the government uncover fraud. *Cf. United States ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 932 (D.C. Cir. 2017). This purpose would be undermined if a relator were permitted to add additional defendants years later—and potentially after the government has declined to intervene.

6. State Law Claims

The briefing on this motion almost exclusively addresses the federal FCA. However, Omni also brings 35 state-law claims alleging violations of different state laws analogous to the FCA. Although these statutes in general mirror the FCA, they are not identical. However, defendants argue that I should treat the state statutes as identical and dismiss the state law claims "for the same reasons" that I dismiss any federal claim. (Defs.' Mem. at 22). However, I cannot simply transfer my reasoning concerning the federal statute to different statutes, particularly when defendants, who are the movants, have provided me with no information concerning those statutes. I cannot

assume those statutes' limitations periods and pleading standards. Therefore, I deny the motion to dismiss as to all state claims.

7. Common Law Claims

Lastly, defendants argue that Omni's common law claims for payment under mistake of fact and unjust enrichment must be dismissed because Omni lacks standing to assert claims to recover damages allegedly suffered by governments. *See U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 452 (S.D.N.Y. 2001). There being no argument in opposition by Omni, the common law claims are dismissed.

IV. Conclusion

Defendants' motion to dismiss the Second Amended Complaint is granted in part and denied in part.

All federal claims (counts 1–4) against US Oncology, Inc. are dismissed without prejudice under the first-to-file bar.

The reverse false claims (count 3), conspiracy (count 4), and common law (counts 5 and 6) claims are dismissed as to all defendants.

All federal claims (counts 1–4) against McKesson Specialty Care Distribution Corporation, McKesson Specialty Care Distribution LLC, McKesson Specialty Care Distribution Joint Venture, L.P., Oncology Therapeutics Network Joint Venture, L.P., and US Oncology Specialty, L.P. are dismissed on statute of limitations grounds. I decline to exercise supplemental jurisdiction over the state law claims asserted against those defendants and US Oncology, Inc. and dismiss those claims without prejudice. The Clerk of Court shall terminate these defendants as parties.

The motion to dismiss is otherwise denied. In sum, the remaining claims are those brought under § 3729(a)(1) for false claims (count 1) and § 3729(a)(2) for false statements (count 2), and

all state statutory claims (counts 7–41). The remaining defendants are McKesson Corporation and Oncology Therapeutics Network Corporation.

SO ORDERED.

/s/ Nina Gershon
NINA GERSHON
United States District Judge

Dated: February 4, 2019
Brooklyn, New York